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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,598	03/01/2002	Donald J. Carano	P-3458C1	7673

7590 08/25/2003

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EXAMINER

MUSSER, BARBARA J

ART UNIT	PAPER NUMBER
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1733

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,598

Applicant(s)

CARANO, DONALD J.

Examiner

Barbara J. Musser

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-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 9-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Claims 9-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai(U.S. Patent 5,033,476) in view of Wermund(U.S Patent 5,472,542) and Knowles(U.S Patent 2,965,932).

Kasai discloses an evacuated blood collection tube which is sealed at one end with a seal comprising a sealing member attached to a stopper(45).(Figure 5) The reference suggests the use of an adhesive to bond the layers together but is silent as to the specifics of the formation process. Wermund discloses forming closures for containers made of a sealing member and a base(a portion that fits into the container), by placing the sealing member in an injection mold and injecting material to form the base to securely bond the seal and base together.(Col. 5, ll. 2-7) It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the

seal of Kasai by injection molding the stopper onto the sealing member since this would securely bond to two together.(Col. 5, ll. 2-7)

The references cited above do not disclose this is a continuous process, where multiple items are made at the same time. Knowles discloses making closures in a continuous process wherein a web of material from a roll is placed in a mold, and material is injection molded to form the closure. The closures are then cut from the web of material.(Figure 1; Col. 4, ll. 35-Col. 5, ll. 10) It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the process of forming the closures of Kasai and Wermund a continuous process as shown by Knowles(Col. 1, ll. 56-64) since this would increase production as is well-known in the art.

Regarding claim 2, since the tubes to which the seals are to be applied are cylindrical, the sealing members and stoppers would be cylindrical.

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai, Wermund, and Knowles as applied to claim above, and further in view of Dawson(U.S. Patent 4,445,836).

The references cited above do not disclose winding the seals on a roll before cutting them from the sealing material. Dawson discloses forming a string of injection molded articles which are wound in a coil so that they can be used in an automated assembly process.(Abstract) It would have been obvious to one of ordinary skill in the art at the time the invention was made to wind the web of preformed seals into a roll and

cut later since this would greatly facilitate its use in an automated assembly process.(Abstract)

5. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai, Wermund, and Knowles as applied to claim 1 above, and further in view of Newby et al.(U.S Patent 6,017,317).

Kasai discloses the sealing member is made from a layer of PET with a metal foil attached thereto which is attached to an adhesive layer.(Col. 8, ll. 8-13) It does not disclose the specific relationship on the metal layer to the adhesive layer. It is well-known and conventional in the blood tube arts to orient the seal such that the metal foil is between the PET and the adhesive as shown for example by Newby et al. which discloses the sealing member has the metal foil between the PET and the adhesive.(Col. 3, ll. 56-65) It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the seal such that the metal foil is between the PET and the adhesive since this is well-known and conventional in the art as shown for example by Newby et al.(Col. 3, ll. 56-65)

Regarding claim 6, Kasai does not disclose the specific adhesive layer which bonds the metal foil to the top of the blood collection tube. Newby et al. discloses the adhesive can be PET.(Col. 3, ll. 56-60) It would have been obvious to one of ordinary skill in the art at the time the invention was made to use any conventional adhesive which is known to be used to bond metal to glass or plastic such as PET, particularly since Newby et al. discloses PET can be used as the adhesive.

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6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai, Wermund, and Knowles as applied to claim 1 above, and further in view of Miller(U.S. Patent 6,039,698).

The reference cited above do not disclose the seal having an outer cap with a skirt which extends down the tube having an annular shoulder extending inward with an aperture at the center. Miller discloses a seal having an outer cap with a skirt which extends down the tube having an annular shoulder extending inward with an aperture at the center and a collar extending upward from the aperture.(Figure 5) It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the cap of Miller on the seal of Kasai, Wermund, and Knowles since this cap would allow separation of the seal from the tube of Kasai while reducing the risk of the technician removing the seal contacting the blood within the tube.(Col. 1, ll. 65- Col. 2, ll. 6)

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai, Wermund, Knowles, and Miller as applied to claim 7 above, and further in view of Yamazaki et al.(U.S Patent 5,326,534).

The references cited above do not disclose a top stopper within the collar extending upward from the aperture of Kasai, Wermund, Knowles, and Miller. Yamazaki et al. discloses a method of sealing blood tubes wherein a rubber stopper is applied to the top of the sealing member.(Figure 1) It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply a top stopper to

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the sealing member of Kasai, Wermund, Knowles, and Miller to help insure the seal re-sealed after use.(Col. 3, ll. 8-14)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Barbara J. Musser** whose telephone number is **(703)-305-1352**. The examiner can normally be reached on Monday-Thursday; alternate Fridays.

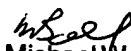
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Ball can be reached on 703-308-2058. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



BJM

August 11, 2003



Michael W. Ball
Supervisory Patent Examiner
Technology Center 1700